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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|----------------------|
| 10/632,413 | 07/31/2003 | Robert E. Richard | 02-264 | 4374 |
| 27774 | 7590 | 05/03/2006 | EXAMINER | |
| MAYER & WILLIAMS PC 251 NORTH AVENUE WEST 2ND FLOOR WESTFIELD, NJ 07090 | | | | HAGOPIAN, CASEY SHEA |
| ART UNIT | | PAPER NUMBER | | |
| | | 1615 | | |

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|------------------------------|------------------------|---------------------|
| | 10/632,413 | RICHARD ET AL. |
| Examiner | Art Unit | |
| | Casey Hagopian | 1615 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 30 January 2006.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-19 is/are pending in the application.
4a) Of the above claim(s) 7-10, 15 and 16 is/are withdrawn from consideration.
5) Claim(s) _____ is/are allowed.
6) Claim(s) 1-6, 11-14 and 17-19 is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/2/04 2/22/05.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____ .

DETAILED ACTION

1. Receipt is acknowledged of applicant's Response to Restriction Requirement filed 1/30/2006.

Election/Restrictions

2. Applicant's election of the following species, a) rubbery phase and b) carrier region, in the reply filed on 1/30/2006 is acknowledged. Because applicant did not distinctly and specifically point out any errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, claims 1-19 are currently pending and claims 7-10, 15 and 16 have been withdrawn.

Claim Objections

3. Claim 5 is objected to because of the following informalities: the word "than" appears to be missing between the words "lower" and "0°C" in the 2nd line of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 1-5, 11-14 and 17-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for poly(methyl methacrylate), poly(ethyl

acrylate), and poly(butyl acrylate), does not reasonably provide enablement for all main chain polymers corresponding to a rubbery phase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. A careful review indicates that the instant specification is not sufficient to support the generic concept of main chain polymers corresponding to a rubbery phase.

6. Claims 1-5, 11-14 and 17-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for poly(styrene) and poly(methyl methacrylate), does not reasonably provide enablement for all side chain polymers corresponding to a hard phase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. A careful review indicates that the instant specification is not sufficient to support the generic concept of side chain polymers corresponding to a hard phase.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-6, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Shah (USPN 5,814,329). Shah teaches a drug delivery system comprising a graft

copolymer and a drug for intravaginal administration (abstract). The graft copolymer comprises a hydrophilic main chain and a hydrophobic side chain, preferably polystyrene (column 4, lines 3-9). The hydrophilic main chain comprises monomeric units having acidic groups and optionally neutral monomeric units including methacrylates (column 4, lines 6-20). Shah further teaches that swellable polymers can also be included in the active drug delivery vehicle (column 4, lines 50-55; column 5, lines 35-40). Thus, the disclosures of Shah render the instant claims anticipated.

Pertinent Art

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chen et al. (US 2003/0039689 A1) teaches a polymer-based, sustained release drug delivery system (title; abstract). Chen specifically exemplifies a coating comprising a poly(ethyl acrylate and methyl methacrylate) copolymer and 5-fluouracil, an anti-neoplastic drug (example 9). Chen further teaches that the coatings may be applied to medical devices including catheters vascular grafts and stents (paragraphs 0037-0038).

Conclusion

10. All claims have been rejected; no claims are allowed.

Correspondence

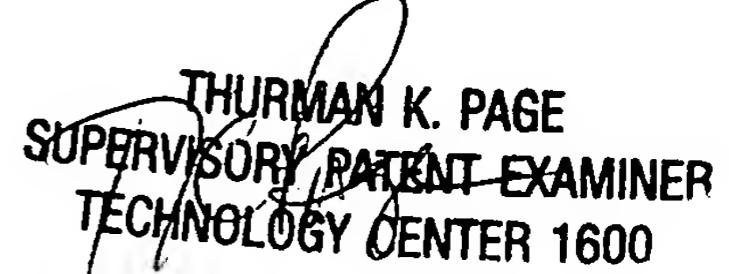
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on M-F from 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Casey Hagopian
Examiner
Art Unit 1615



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